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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,484	01/28/2000	Adriaan Anthonius Wilhelmus Marie Van Loon	1999.454 US	2307

7590 01/02/2002

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EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/493,484	Van Loon, A.
Examiner	**Art Unit**
Jeffrey S. Parkin, Ph.D.	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *24 Oct 2001*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above, claim(s) *1-4, 10-13, and 15* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *5-9 and 14* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Detailed Office Action

Status of the Claims

1. Applicant's election with traverse of Group II (claims 5-9 and 14) in paper no. 6 is acknowledged. The traversal is based upon the premise that the claims are all commonly related to a particular avian reovirus and would not constitute an undue burden if examined concomitantly. This is not found persuasive for the reasons of record previously set forth in paper no 5. The restriction requirement was clearly stated in the Office action as set forth below:

> 1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
>
> a. Group I, claim(s) 1-4 and 13, drawn to an **avian reovirus**, classified in class 435, subclass 235.1.
>
> b. Group II, claim(s) 5-9 and 14, drawn to a **vaccine** comprising an **avian reovirus** and a **pharmaceutically acceptable diluent**, classified in class 424, subclass 215.1.
>
> c. Group III, claim(s) 10, drawn to a **method** for the **preparation** of **avian reoviruses**, classified in class 435, subclass 239.
>
> d. Group IV, claim(s) 11, 12, and 15[1], drawn to a **method** for the **preparation** of a **vaccine**, classified in class 435, subclass 236.
>
> 2. The inventions are distinct, each from the other because of the following reasons:
>
> 3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have

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[1] Claim 15, which is directed toward claim 10, actually appears to be directed toward a method of preparing a vaccine (claim 11) since it involves a viral inactivation step and the addition of a carrier or diluent. Accordingly, it has been included in Group IV (claims 11 and 12). If the claim is not directed toward such a method, appropriate clarification and amendment will be required.

different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, the reovirus of Group I can be employed in a number of different biochemical assays (i.e., infectivity, ligand-binding, affinity chromatography) while the pharmaceutical composition of Group II, which has a different composition and attendant products that comprise it, can be employed in materially different processes such as vaccination and therapeutic applications. Therefore, each invention is clearly drawn toward a different inventive entity.

4. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, each of the groups identified is directed toward a different scientific objective (i.e., the preparation of virus or a vaccine) that employs materially different reagents and assay steps. Accordingly, each invention is clearly drawn toward a different inventive concept.

5. Inventions I and IV, and II and III, respectively, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (refer to M.P.E.P. ¶s 806.04 and 808.01). In the instant case, neither of the methods requires the products of the corresponding groups. Therefore, each invention is clearly drawn toward a different inventive entity.

6. Inventions I and III are related as product made and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different products, **or** (2) the product as claimed can be made by another and materially different process (M.P.E.P. ¶ 806.05(f)). In the instant case, the reovirus of Group I can be prepared through alternative methodologies such a PCR amplification from the host of interest or through selective culturing techniques.

7. Inventions II and IV are related as product made and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed can be used to make other and materially different products, **or** (2) the product as claimed can be made by another and materially different process (M.P.E.P. ¶ 806.05(f)). In the instant case, the vaccine of Group II can be prepared through alternative methodologies such as PCR amplification, selective culturing, or physical/chemical inactivation.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, requirement for independent searches, and

recognized divergent subject matter, restriction for examination purposes as indicated is proper. **Applicant is required under 35 U.S.C. § 121 to elect a single group for prosecution on the merits.** Applicants are also reminded that the claims should be amended, if necessary, to reflect the election.

Applicant is reminded that **establishment of *prima facie* evidence for a serious burden requires the demonstration, by appropriate explanation, of either separate classification, separate status in the art, or a different field of search as defined in M.P.E.P. § 808.02.** As set forth in the original restriction requirement, different classifications are present for each group and separate searches will be required for each invention. Therefore, **the restriction requirement is still deemed to be proper and is therefore made FINAL.** Claims 1-4, 10-13, and 15 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Drawings

2. The drawings filed in this application are objected to by the Draftsperson under 37 C.F.R. § 1.84 or 1.152 as indicated. These drawings are acceptable for examination purposes only. Formal drawings with the appropriate corrections will be required when the application is allowed. Applicants are reminded to amend the specification (i.e., brief description of the figures including panel descriptions) if necessary when submitting corrected drawings.

Information Disclosure Statement

3. The information disclosure statement filed 28 January, 2000, has been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 112, Second Paragraph

4. Claims 5-9 and 14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite for referencing limitations in a non-elected claim. Applicants are reminded of the original restriction requirement set forth in paper no. 5. The claim language should be amended to reflect this requirement (i.e., A vaccine composition comprising an avian reovirus ... and a pharmaceutically acceptable carrier or diluent). The claims are also vague and indefinite for failing to clearly set forth the salient features and characteristics of the vaccine stock. For instance, does the vaccine stock comprise a live virus, attenuated virus, or an inactivated virus? Does the stock comprise a single purified viral stock (e.g., an isolated and purified avian reovirus having the E.C.A.C.C. accession no. 99011475) or a collection of different viruses? The reference to "one or more vaccine components" is vague and indefinite since the precise structure and composition of these components is not set forth.

35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 5-8 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Page *et al.* (1984). This teaching discloses the preparation of poultry vaccines comprising an avian reovirus (e.g.,

strain CO_8). The vaccine strain was isolated from poultry using the same materials and methods described by applicants. While the reference relied upon does not disclose the use of a plaque reduction assay in further characterizing the virus, nevertheless, this virus appears to display the same genotypic and phenotypic characteristics as that of the instantly claimed virus.

7. Claims 5-7, 9, and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rosenberger *et al.* (1995). This teaching discloses the preparation of poultry vaccines comprising an avian reovirus (e.g., strain 2177). The vaccine strain was isolated from poultry using the same or similar materials and methods described by applicants. While the reference relied upon does not disclose the use of a plaque reduction assay in further characterizing the virus, nevertheless, this virus appears to display the same genotypic and phenotypic characteristics as that of the instantly claimed virus.

35 U.S.C. § 103(a)

8. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

10. Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenberger *et al.* (1995). While this teaching does not explicitly describe a vaccine composition comprising an avian reovirus vaccine strain and an adjuvant, it does however state (see p. 3, lines 35-45) that "one or more compounds having adjuvant activity may be added as well. Any conventional stabilizers and adjuvants may be included in a vaccine according to this invention." Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare a vaccine composition comprising an avian reovirus vaccine strain and an art-recognized adjuvant since this would result in a stronger immune response against the immunogen.

Additional Prior Art

11. The following prior art, which was not relied upon in the office action, is considered germane to applicant's disclosure:

- "Avian proventriculitis vaccine", Page, R. K., *et al.*, U.S. Patent No. 4,559,229, published 12/17/85.
- "Reovirus strain 2177 and vaccine containing same", Rosenberger, J. K., *et al.*, U.S. Patent No. 5,525,342, published 06/11/96.

Correspondence

12. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

13. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

28 December, 2001